We claim:

1. A method for predicting the level and distribution of CYP3A5 expression in a subject comprising determining the nucleotide present in each CYP3A5 allele of the genomic DNA of said subject at the location(s) selected from the group consisting of:

(a) the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 within intron 3 of the Cyp3A5 gene;

(b) the position corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 within exon 7 of the Cyp3A5 gene; and

(c) the positions corresponding to both nucleotide 22,893 and nucleotide 30,597 of Genbank sequence accession no. AC005020;

wherein the presence of an A at the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 on at least one CYP3A5 allele of said subject predicts a relatively high level of expression of CYP3A5 and the presence of a G at the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 on each CYP3A5 allele of said subject predicts a relatively low level of expression;

wherein the presence of a G at the position corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 on at least one CYP3A5 allele of said subject predicts a relatively high level of expression of CYP3A5 and the presence of an A at the position corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 on each CYP3A5 allele of said subject predicts a relatively low level of expression of CYP3A5; and

wherein the presence of an A at the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 and a G at the position corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 on at least one CYP3A5 allele of said subject predicts a relatively high level of expression of CYP3A5 and the presence of either a G at the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 or an A at the position

corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 on each CYP3A5 allele of said subject predicts a relatively low level of expression of CYP3A5.

2. The method of claim 1 wherein said location is the position corresponding to nucleotide 22,893 of Genbank sequence accession no. AC005020 within intron 3 of the Cyp3A5 gene.

3. The method of claim 1 wherein said location is the position corresponding to nucleotide 30,597 of Genbank sequence accession no. AC005020 exon 5 of the Cyp3A5 gene.

4. The method of claim 1 wherein said locations are the positions corresponding to both nucleotide 22,893 and nucleotide 30597 of Genbank sequence accession no. AC005020.

5. The method of claims 1-4 wherein the step of determining the nucleotide present in each CYP3A5 allele of said subject at the selected location(s) is accomplished by sequencing a region of the genomic DNA of said subject which includes said location(s).

6. The method of claims 1-4 wherein the step of determining the nucleotide present in each Cyp3A5 allele of said subject at the selected location(s) is accomplished by (a) amplifying a region of the genomic DNA of said subject which includes said location(s)to generate an amplified fragment, and (b) treating the amplified fragment with a restriction enzyme in its corresponding restriction buffer to determine the identity of the nucleotide present at the selected location(s).

7. The method of claims 1-4 wherein the step of determining the nucleotide present in each Cyp3A5 allele of said subject at the selected location(s) is accomplished by (a) amplifying a region of the genomic DNA of said subject which includes said location(s), and (b) hybridizing the amplified region with probes specific for the

selected location(s) wherein hybridization determines the identity of the nucleotide present at the selected location(s).

8. A method for determining the cytochrome P450 3A5 (CYP3A5) genotype and phenotype of an individual comprising:

(a) isolating nucleic acid from the individual;

(b) amplifying a region of the cytochrome P450 3A5 (*CYP3A5*) gene sequence selected from the group of :

(i) intron 3 comprising nucleotide 22,893 of Genbank accession no. AC005020;

(ii) exon 7 comprising nucleotide 30,597 of Genbank accession no. AC005020; and

(iii) intron 3 comprising nucleotide 22,893 of Genbank accession no. AC005020 and exon 7 comprising nucleotide 30,597 of Genbank accession no. AC005020; ; and

(c) analyzing the cytochrome P450 3A5 (*CYP3A5*) sequence.

9. The method of claim 8 wherein the intron 3 region of cytochrome P450 3A5 (CYP3A5) is amplified utilizing primers which amplify 5' and 3' of the nucleotide 22,893 of Genbank accession no. AC005020.

10. The method of claim 9 wherein the intron 3 region is amplified utilizing primer pairs SEQ ID NO: 24 and 25, or primer pairs SEQ ID NO: 26 and 27.

11. The method of claim 8 wherein the exon 7 region of cytochrome P450 3A5 (CYP3A5) is amplified utilizing primers which amplify 5' and 3' of the nucleotide 30,597 point mutation of Genbank accession no. AC005020.

12. The method of claim 11 wherein the exon 7 region is amplified utilizing primer pairs SEQ ID NO: 30 and 16, or primer pairs SEQ ID NO: 31 and 32.

13. A method for determining cytochrome P450 3A5 (CYP3A5) intron 3 genotype of a subject which comprises:

(a) isolating nucleic acid from said subject;

(b) amplifying a cytochrome P450 3A5 (CYP3A5) PCR fragment from said nucleic acid using a set of primers, wherein said set of primers contains primer X and primer Y; wherein

(i) the X primer is complementary to a region 5' to the point mutation site at nucleotide 22,893 of Genbank accession no. AC005020;

(iii) the Y primer is complementary to a region 3' to the point mutation site at nucleotide 22,893 of Genbank accession no. AC005020;

(c) amplifying the sequence in between primers X and Y, thereby obtaining an amplified fragment; and

(d) sequencing the amplified fragment obtained in step (c), thereby determining the cytochrome P450 3A5 (CYP3A5) intron 3 genotype of said subject.

14. The method of claim 13 wherein primer X has the sequence corresponding to SEQ ID NO: 24, or a fragment thereof which is at least ten bases long, and primer Y has the sequence corresponding to SEQ ID NO: 25 , or a fragment thereof which is at least ten bases long.

15. The method of claim 13 wherein primer X has the sequence corresponding to SEQ ID NO: 26 , or a fragment thereof which is at least ten bases long, and primer Y has the sequence corresponding to SEQ ID NO: 27 , or a fragment thereof which is at least ten bases long.

16. A method for determining cytochrome P450 3A5 (CYP3A5) genotype of a subject which comprises:

(a) isolating nucleic acid from said subject;

(b) making a first and a second PCR primer wherein

(i) the first PCR primer is complementary to intron 3 and introduces a base change in the PCR product adjacent to or near the point mutation at nucleotide 22,893

of Genbank accession no. AC005020, such that a restriction site is generated in the presence of a particular nucleotide at nucleotide 22,893; and

(ii) the second PCR primer is complementary to a region 3' to the intron 3 nucleotide 22,893 of Genbank accession no. AC005020;

(c) amplifying the sequence in between the first and the second primers; thereby obtaining an amplified fragment; and

(d) treating the amplified fragment obtained in step (c) with a restriction enzyme in its corresponding restriction buffer to detect presence or absence of a point mutation at nucleotide 22,893 of Genbank accession no. AC005020, thereby determining the cytochrome P450 3A5 (CYP3A5) genotype of said subject.

17. The method of claim 16 wherein the first primer introduces a *Tru9* I/*Mse*I restriction site in the presence of an A nucleotide at nucleotide 22,893, and the second primer has the sequence selected from SEQ ID NO:27 and SEQ ID NO: 25, or a fragment thereof which is at least ten bases long.

18. The method of claim 16 wherein the first primer has the sequence corresponding to SEQ ID NO: 33, or a fragment thereof which is at least ten bases long, and the second primer has the sequence corresponding to SEQ ID NO: 27, or a fragment thereof which is at least ten bases long.

19. The method of claim 16 wherein the first primer has the sequence corresponding to SEQ ID NO:33 , or a fragment thereof which is at least ten bases long, and the second primer has the sequence corresponding to SEQ ID NO:25, or a fragment thereof which is at least ten bases long.

20. A method for determining cytochrome P450 3A5 (CYP3A5) genotype of a subject which comprises:

(a) isolating nucleic acid from said subject;

(b) amplifying a cytochrome P450 3A5 (CYP3A5) PCR fragment from said nucleic acid using a first set of primers, wherein said first set of primers contains primer X and primer Y; wherein

(i) the X primer is complementary to a region 5' to the point mutation site at nucleotide 22,893 of Genbank accession no. AC005020; and

(ii) the Y primer is complementary to a region 3' to the point mutation site at nucleotide 22,893 of Genbank accession no. AC005020;

(c) amplifying the sequence in between primers X and Y, thereby obtaining an first round amplified fragment;

(d) amplifying the first round amplified fragment using a second set of primers, wherein said second set of primers contains primer Z and primer W, wherein

(i) primer Z is complementary to intron 3 and introduces a base change in the PCR product adjacent to or near the point mutation at nucleotide 22,893 of Genbank accession no. AC005020, such that a restriction site is generated in the presence of a particular mutation at nucleotide 22,893; and

(ii) primer W is complementary to a region 3' to intron 3;

(e) amplifying the sequence in between primers Z and W, thereby obtaining an amplified fragment; and

(f) treating the amplified fragment obtained in step (e) with a restriction enzyme in its corresponding restriction buffer to detect presence or absence of a point mutation at nucleotide 22,893 of Genbank accession no. AC005020, thereby determining the cytochrome P450 3A5 (CYP3A5) genotype of said subject.

21. The method of claim 20 wherein primer X has the sequence corresponding to SEQ ID NO: 24, or a fragment thereof which is at least ten bases long; primer Y has the sequence selected from the group of SEQ ID NO:25, or a fragment thereof which is at least ten bases long; primer Z introduces a *Tru9* I/*Mse*I restriction site in the presence of an A nucleotide at nucleotide 22,893 of Genbank accession no. AC005020; and primer W has the sequence selected from SEQ ID NO: 27 and SEQ ID NO: 25, or a fragment thereof which is at least ten bases long.

22. The method of claim 21 wherein primer Z has the sequence corresponding to SEQ ID NO: 33 , or a fragment thereof which is at least ten bases long.

23. A method for determining cytochrome P450 3A5 (CYP3A5) genotype of a subject which comprises

(a) isolating nucleic acid from said subject;

(b) amplifying a cytochrome P450 3A5 (CYP3A5) PCR fragment from said nucleic acid using a set of primers, wherein said set of primers contains primer X and primer Y; wherein

(i) the X primer is complementary to a region 5' to the point mutation site at nucleotide 30,597 of Genbank accession no. AC005020;

(iii) the Y primer is complementary to a region 3' to the point mutation site at nucleotide 30,597 of Genbank accession no. AC005020;

(c) amplifying the sequence in between primers X and Y, thereby obtaining an amplified fragment; and

(d) sequencing the amplified fragment obtained in step (c), thereby determining the cytochrome P450 3A5 (CYP3A5) exon 7 genotype of said subject.

24. The method of claim 23 wherein primer X has the sequence corresponding to SEQ ID NO: 30, or a fragment thereof which is at least ten bases long, and primer Y has the sequence corresponding to SEQ ID NO: 16 , or a fragment thereof which is at least ten bases long.

25. The method of claim 23 wherein primer X has the sequence corresponding to SEQ ID NO: 31, or a fragment thereof which is at least ten bases long, and primer Y has the sequence corresponding to SEQ ID NO: 32 , or a fragment thereof which is at least ten bases long.

26. A method for determining cytochrome P450 3A5 (CYP3A5) genotype of a subject which comprises:

(a) isolating nucleic acid from said subject;

(b) making a first and a second PCR primer wherein

(i) the first PCR primer is complementary to exon 7 and introduces a base

change in the PCR product adjacent to or near the point mutation at nucleotide 30,597 of Genbank accession no. AC005020, such that a restriction site is generated in the presence of a particular nucleotide at nucleotide 30,597; and

(ii) the second PCR primer is complementary to a region 3' to the intron 3 nucleotide 30,597 of Genbank accession no. AC005020;

(c) amplifying the sequence in between the first and the second primers; thereby obtaining an amplified fragment; and

(d) treating the amplified fragment obtained in step (c) with a restriction enzyme in its corresponding restriction buffer to detect presence or absence of a point mutation at nucleotide 30,597 of Genbank accession no. AC005020, thereby determining the cytochrome P450 3A5 (CYP3A5) genotype of said subject.

27. The method of claim 26 wherein the first primer introduces a *Tru9* I/*Mse*I restriction site in the presence of a A nucleotide at nucleotide 30,597 of Genbank accession no. AC005020, and the second primer has the sequence selected from SEQ ID NO: 32 and SEQ ID NO: 16 , or a fragment thereof which is at least ten bases long.

28. The method of claim 26 wherein the first primer has the sequence corresponding to SEQ ID NO: 34, or a fragment thereof which is at least ten bases long, and the second primer has the sequence corresponding to SEQ ID NO: 32, or a fragment thereof which is at least ten bases long.

29. The method of claim 26 wherein the first primer has the sequence corresponding to SEQ ID NO: 34, or a fragment thereof which is at least ten bases long, and second primer has the sequence corresponding to SEQ ID NO: 16, or a fragment thereof which is at least ten bases long.

30. A method for determining cytochrome P450 3A5 (CYP3A5) exon 7 genotype of a subject which comprises:

(a) isolating nucleic acid from said subject;

(b) amplifying a cytochrome P450 3A5 (CYP3A5) PCR fragment from said nucleic

acid using a first set of primers, wherein said first set of primers contains primer X and primer Y; wherein

(i) the X primer is complementary to a region 5' to the point mutation site at nucleotide 30,597 of Genbank accession no. AC005020;

(ii) the Y primer is complementary to a region 3' to the point mutation site at nucleotide 30,597 of Genbank accession no. AC005020;

(c) amplifying the sequence in between primers X and Y, thereby obtaining an first round amplified fragment;

(d) amplifying the first round amplified fragment using a second set of primers, wherein said second set of primers contains primer Z and primer W, wherein

(i) primer Z is complementary to exon 7 and introduces a base change in the PCR product adjacent to or near the point mutation at nucleotide 30,597 of Genbank accession no. AC005020, such that a restriction site is generated in the presence of a particular mutation at nucleotide 30,597 of Genbank accession no. AC005020; and

(ii) primer W is complementary to a region 3' to exon 7;

(e) amplifying the sequence in between primers Z and W, thereby obtaining an amplified fragment; and

(f) treating the amplified fragment obtained in step (e) with a restriction enzyme in its corresponding restriction buffer to detect presence or absence of a point mutation at nucleotide 30,597 of Genbank accession no. AC005020, thereby determining the cytochrome P450 3A5 (CYP3A5) genotype of said subject.

31. The method of claim 30 wherein primer X has the sequence corresponding to SEQ ID NO: 30, or a fragment thereof which is at least ten bases long; primer Y has the sequence of SEQ ID NO: 16, or a fragment thereof which is at least ten bases long; primer Z introduces a *Tru9* I/*Mse*I restriction site in the presence of an A nucleotide at nucleotide 30,597; and primer W has the sequence selected from SEQ ID NO: 32 and SEQ ID NO:16 , or a fragment thereof which is at least ten bases long.

32. The method of claim 31 wherein primer Z has the sequence corresponding to SEQ ID NO: 34, or a fragment thereof which is at least ten bases long.

33. A test kit suitable for determining cytochrome P450 3A5 (CYP3A5) genotype, and thereby determining expression of cytochrome P450 3A5 (CYP3A5) protein in an individual comprising:

(a) a predetermined amount of a first amplification primer complementary to a region 5' to nucleotide 22,893 of Genbank accession no. AC005020 within intron 3 of the CYP3A5 gene;

(b) a predetermined amount of a second amplification primer complementary to a region 3' to nucleotide 22,893 of Genbank accession no. AC005020 within intron 3 of the CYP3A5 gene;

(c) other reagents; and

(d) directions for use of said kit.

34. The test kit of claim 33 wherein the first amplification primer has the sequence corresponding to SEQ ID NO: 24 or SEQ ID NO: 26 and the second amplification primer has the sequence corresponding to SEQ ID NO: 25 or SEQ ID NO:27.

35. A test kit suitable for determining cytochrome P450 3A5 (CYP3A5) genotype, and thereby determining expression of cytochrome P450 3A5 (CYP3A5) protein in an individual comprising:

(a) a predetermined amount of a first amplification primer complementary to a region 5' to nucleotide 30,597 of Genbank accession no. AC005020 within exon 7 of the CYP3A5 gene;

(b) a predetermined amount of a second amplification primer complementary to a region 3' to nucleotide 30,597 of Genbank accession no. AC005020 within exon 7 of the CYP3A5 gene;

(c) other reagents; and

(d) directions for use of said kit.

36. The test kit of claim 35 wherein the first amplification primer has the sequence corresponding to SEQ ID NO: 30 or SEQ ID NO: 31 and the second amplification primer has the sequence corresponding to SEQ ID NO: 16 or SEQ ID NO:32.

37. An isolated oligonucleotide primer having a sequence selected from the group of SEQ ID NOS: 24-27 and 33 or a fragment thereof which is at least ten bases long.

38. An isolated oligonucleotide primer having a sequence selected from the group of SEQ ID NOS: 16, 30-32 and 34 or a fragment thereof which is at least ten bases long.